

### **REMARKS**

Claims 40-71 and 77, 78, and 82-145 are pending in this application. Claims 82-96, 99-122, and 124-145 stand rejected. No claims stand objected to. Claims 40-56, 77, and 78 are withdrawn, as they are drawn to non-elected groups/species. Claims 40-56, 77, and 78 are withdrawn from consideration, as being drawn to non-elected subject matter. The Applicants respectfully dispute the Examiner characterization on the Office Action Summary page that Claims 97, 98, 123, and 124 are withdrawn from consideration. Rather, Claims 97, 98, 123, and 124 are drawn to the elected subject matter of vaccine compositions comprising live attenuated rotavirus populations, and are therefore still under examination in this application. The Applicants herein cancel Claims 83-91, 93, 116-119, and 121-145 without prejudice or disclaimer to the subject matter contained therein. The Applicants herein amend Claims 93-95, 113-115, and 120 to clarify the instantly claimed subject matter. Claim 93, as amended, now incorporates all of the limitations in cancelled Claim 92. Also, the Applicants herein add new Claim 146. These amended and new claims find support in the as-filed specification and claims. Accordingly, none of these amendments raises any issue of new matter.

The Applicants acknowledge with appreciation the courtesy that Examiner Humphrey and her Primary Examiner, Examiner Parkin, extended to Ms. Hecht and Dr. Crepin in the telephonic interview held on 16 November 2006. The interview focused on the section 112 rejections relating to the claim phrase, "substantially single variant". Specifically, Ms. Hecht and Dr. Crepin talked about various claim amendments that they hoped would obviate these rejections.

### **CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 82-145 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Specifically, the Examiner contends that it is not clear what the phrase "a single variant or a substantially single variant" means in these claims. The Applicants herein cancel Claims 83-91, 93, 116-119, and 121-145 without prejudice or disclaimer. In addition, the Applicants herein amend Claims 93 and 94 (and dependent Claims 95-115, and 120 to delete the phrase, "substantially single variant". Also, new Claim 146 does not recite this phrase.

Claims 82, 84, and 86 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for reciting the phrase, "encoding at least one of the major viral

proteins designated as VP4 and VP7". The Applicants herein cancel Claims 82, 84, and 86 without prejudice or disclaimer. Also, none of the amended claims or new Claim 146 contains this phrase.

For all of the above reasons, the Applicants respectfully assert that Claims 92, 94-115, and 120, as amended, as well as new Claim 146, are sufficiently definite. Accordingly, they request reconsideration and withdrawal of all of the grounds of rejection of these claims under 35 U.S.C. § 112, second paragraph.

#### **CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

Claims 82-85, 95, 96, 99, 100, 113-115, 121, 122, 125, 126, and 132 stand rejected as allegedly anticipated by Burke, *et al.* (US 5,932,223) under 35 U.S.C. § 102(b). The Applicants herein cancel Claims 82-85, 121, 122, 125, 126, and 132 without prejudice or disclaimer. In addition, the Applicants herein amend Claims 95, 96, 99, 100, 113-115, 121, 122, 125, 126, and 132 to depend from non-rejected Claim 94, as amended. The Applicants submit that Burke, *et al.* fails to identically disclose the instantly claimed rotavirus variant, P43 that contains all 6 of the nucleotide mutations recited in Claim 94, as amended, and that contains all 2 of the amino acid mutations recited in Claim 92, as amended. Therefore, Burke, *et al.* does not anticipate any of the instantly pending claims.

In addition, Claims 82-85, 113-115, and 139-141 stand rejected as allegedly anticipated by Hoshino, *et al.* (US2002/0058043) under 35 U.S.C. § 102(e). The Applicants herein cancel Claims 82-85, and 139-141 without prejudice or disclaimer. In addition, the Applicants herein amend Claims 113-114 to depend from non-rejected Claim 94, as amended. The Applicants submit that Hoshino, *et al.* fails to identically disclose the instantly claimed rotavirus variant, P43 that contains all 6 of the nucleotide mutations recited in Claim 94, as amended, or that contains all 2 of the amino acid substitutions recited in Claim 92, as amended. Therefore, Hoshino, *et al.* does not anticipate any of the instantly pending claims. Accordingly, these anticipation rejections are all moot. The Applicants respectfully request reconsideration and withdrawal of all of these claim rejections under 35 U.S.C. § 102.

#### **CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

Claims 82-85, 109, and 135 stand rejected under 35 U.S.C. § 103, as allegedly unpatentable over Hoshino, *et al.* in view of Chen, *et al.* (US 6,552,024). The Applicants

herein cancel Claims 82-85, and 135. The Applicants amended Claim 109 to depend from non-rejected Claim 94. Therefore, this ground of rejection is moot.

In addition, Claims 82-85, 101-104, 106, 108, 110, 112, 127-130, 134, 136, and 138 stand rejected under 35 U.S.C. § 103, as allegedly unpatentable over Hoshino, *et al.* in view of Tsutsumi, *et al.* (US 4,152,421). The Applicants herein cancel Claims 82-85, 127-130, 134, 136, and 138 without prejudice or disclaimer. The Applicants herein amend Claims 101-104, 106, 108, 110, and 112 to depend from non-rejected Claim 94. Therefore, this ground of rejection is moot.

Lastly, Claims 82-85, 105, 107, 111, 131, 133, and 137 stand rejected as allegedly unpatentable over Hoshino, *et al.* in view of Tsutsumi, *et al.* (US 4,152,421), and further in view of the Therapeutic Goods Administration in the Department of Community Services and Health in Australia (1991). The Applicants herein cancel Claims 82-85, 131, 133, and 137. In addition, the Applicants herein amend Claims 105, 107, and 111 to depend from non-rejected Claim 94, as amended. Therefore, this ground of rejection is moot. In view of the amendments contained herein, the Applicants respectfully request reconsideration and withdrawal of all of these rejections under 35 U.S.C. § 103.

#### **NEW REJECTIONS – 35 U.S.C. § 112, WRITTEN DESCRIPTION & ENABLEMENT**

Claims 82-86, 89, 92-94, 116, 117, and 142 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The basis of these rejections appears to stem from the phrase, “substantially single variant”, which can comprise up to 10% variation from the disclosed sequences. The Applicants herein cancel Claims 82-86, 89, 93, 116, 117, and 142 without prejudice or disclaimer. Furthermore, the Applicants herein amend Claim 92 and 94 to delete the phrase, “substantially single variant”. Therefore, the Applicants submit that this ground of rejection of Claims 92 and 94, as amended, is now moot.

Claims 82-88, 92, 93, 95, 96, 99-119, 121, 122, and 125-144 stand rejected under 35 U.S.C. § 112, first paragraph, enablement requirement. Specifically, while the Examiner admits that the specification is enabling for a vaccine composition containing P43 with all six mutations present in VP4 and VP7 regions, he alleges that the specification does not reasonably provide enablement for any single or other multiple mutation.

The Applicants herein cancel Claims 82-88, 93, 116-119, 121, 122, and 125-144 without prejudice or disclaimer. The Applicants herein amend Claims 95, 96, and 99-115 to depend from non-rejected Claim 94, which contains all six disclosed nucleotide mutations in the VP4 and VP7 regions. In addition, as noted above, the Applicants herein amend Claim 92 to recite all two amino acid mutations in the VP4 and VP7 regions. Therefore, this ground of rejection is now moot. Accordingly, the Applicants respectfully request reconsideration and withdrawal of all of the new rejections under 35 U.S.C. § 112, first paragraph, written description and enablement.

**NEW REJECTIONS – 35 U.S.C. § 102 or § 103**

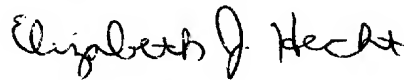
Claims 82-94, 116-120, and 142-145 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103 as allegedly obvious over Hosino, *et al.* The basis of this rejection appears to stem from the recitation of the phrase, “substantially single variant” in these claims, and appears to extend to variants whose phenotypes are not described in the as-filed specification. The Applicants herein cancel Claims 82-91, 93, 116-119, and 142-145 without prejudice or disclaimer. The Applicants herein amend Claims 92 and 94 to delete the phrase, “substantially single variant”, and further amend Claim 120 to depend from Claim 94, as amended. In view of these amendments, to Claims 94 and 120 to recite the live attenuated human rotavirus population, P43, which is disclosed in the specification, these rejections are now moot. In view of the amendments contained herein, the Applicants respectfully request reconsideration and withdrawal of these new rejections of Claims 94 and 120, as amended, under 35 U.S.C. § 102 or, in the alternative, § 103.

The Applicants thank the Examiner for the Office Action, and believes that this they have fully responded to the Office Action. The Applicant reserves the right to prosecute, in one or more patent applications, the cancelled claim, the claims as originally filed, and any other claim that is supported by the instant specification. In view of the foregoing amendments and remarks, the Applicant respectfully submits that the subject application is in condition for allowance. If the Examiner has any remaining objections or concerns, she may

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contact the Applicants' undersigned attorney at the below telephone number to resolve such issues and advance this application to issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Elizabeth J. Hecht". The signature is fluid and cursive, with the first name "Elizabeth" and last name "Hecht" clearly distinguishable.

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